

Elizabeth Kavalier, M.D.

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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

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IN RE: ETHICON, INC.,	:Master File No.
PELVIC REPAIR SYSTEMS	:2:12-MD-02327
PRODUCTS LIABILITY	:MDL 2327
LITIGATION	:JOSEPH R. GOODWIN
	:U.S. DISTRICT JUDGE
JO HUSKEY AND ALLEN	:
HUSKEY	:
vs.	:Case No. 2:12-cv-05201
ETHICON, INC., et al.	:
and	:
	:
TONYA AND GARY EDWARDS	:
vs.	:Case No. 2:12-cv-09972
ETHICON, INC., et al.	:
	:
	:

APRIL 8, 2014

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Oral deposition of ELIZABETH  
KAVALER, M.D., taken pursuant to notice,  
was held at the law offices of Riker,  
Danzig, Scherer, Hyland & Perretti, LLP,  
500 Fifth Avenue, New York, New York 10110,  
commencing at 8:20 a.m., on the above date,  
before Amanda Dee Maslynsky-Miller, a  
Certified Realtime Reporter and Notary  
Public in and for the State of New York.

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1 stuff like that, which --

2 Q. Which you disagree even  
3 occurs?

4 A. Yes.

5 I also don't think it causes  
6 severe chronic pain syndromes, that pain  
7 can come from any surgery, I don't think  
8 it's specific to mesh or no mesh.

9 The IFU, I disagree that it  
10 was incomplete and inaccurate.

11 So I don't know if you want  
12 to go through all of those. But the IFU  
13 goes through the steps to do the TVT-O.  
14 That's it, it's not a sling IFU, it's not  
15 an incontinence IFU. It's a TVT-O IFU  
16 only.

17 It's not designed for use --  
18 I'm not sure what he's referring to.  
19 He'd have to explain what he means with  
20 specific patient population.

21 Q. Which number is that?

22 A. That's letter I.

23 Q. Okay.

24 A. And J is, Ethicon's

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1 marketing was inaccurate and incomplete.

2 I don't agree with that.

3 They came to me, they asked me if I was  
4 interested in a cadaver lab, that was the  
5 marketing that I got from them.

6 Q. So this is one that you're  
7 disagreeing on personal --

8 A. On my personal level.  
9 Because I don't know about -- I didn't  
10 experience the mass marketing strategy.

11 Q. And you haven't looked into  
12 that? That's not something you've done  
13 as part of your --

14 A. No, I didn't. No, I didn't  
15 get into that.

16 And inaccurate -- patient  
17 marketing was inaccurate and incomplete.  
18 This is patient marketing. I don't use  
19 patient brochures, but I certainly have  
20 read through them. And the AUA puts out  
21 a patient brochure, a lot of  
22 organizations that are not marketed put  
23 out patient brochures. And the Ethicon  
24 patient brochure is no different than

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1 anybody else's.

2 Q. Do you still have some of  
3 the patient brochures that were given for  
4 this product?

5 A. No, because I don't use  
6 patient brochures. I have my own.

7 Q. You don't use them?

8 A. No, I use my own. I make up  
9 my own.

10 And then, Their collection  
11 and reporting of postmarketing adverse  
12 events was inaccurate and incomplete.

13 I disagree with that,  
14 because we have studies. And I think  
15 that their -- whatever the company did is  
16 not as important, to me, as what -- the  
17 studies that were done, the randomized  
18 control, some of which did come from the  
19 company, but many which did not, really  
20 speak more to all the things I'm  
21 concerned about.

22 Q. So that's not referring to  
23 any researcher understanding that you  
24 have of the internal things that were or

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1           Q.     I think you testified that  
2     all of the stress incontinence surgeries  
3     have potential complications and risks;  
4     is that correct?

5           A.     That's right.

6           Q.     You earlier testified to  
7     plaintiffs' counsel that you believe that  
8     the TVT-O IFU and warnings were adequate.

9                     My question to you is, was  
10    that from your perspective as a surgeon  
11    who does these type of surgeries?

12          A.     That's my perspective, yes.  
13    As a surgeon in general, whenever you're  
14    given a new product, the IFU doesn't  
15    really -- in my experience, in my  
16    opinion, and I think most of us would  
17    agree, the IFU doesn't tell you anything  
18    about complications of the type of  
19    surgery, just of that specific product.

20          Q.     And is that also from your  
21    perspective as a pelvic floor surgeon who  
22    reads the medical literature concerning  
23    the types of procedures that are out  
24    there to surgically treat stress

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1 incontinence?

2 A. Yes. So if anybody -- you  
3 don't look to the company to teach you  
4 how to operate. You look to the company  
5 to provide the product so you can decide  
6 whether you're going to use it the way  
7 you want to or not.

8 They don't teach you how to  
9 operate.

10 Q. Plaintiffs' counsel asked  
11 you some questions about your experience  
12 in dealing with complications following a  
13 mesh sling surgery.

14 Have you also treated  
15 complications following a non-mesh stress  
16 urinary incontinence surgery?

17 A. Sure.

18 Q. I believe one of the  
19 opinions in Dr. Blaivas's report stated,  
20 and I'll just summarize it, that in his  
21 opinion, TVT-O was defective.

22 Do you believe TVT-O is  
23 defective?

24 A. I do not.

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1 CERTIFICATE

2

3

4 I HEREBY CERTIFY that the  
5 witness was duly sworn by me and that the  
6 deposition is a true record of the  
7 testimony given by the witness.

8

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Amanda Maslynsky-Miller

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Certified Realtime Reporter

Dated: April 22, 2014

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17 (The foregoing certification  
18 of this transcript does not apply to any  
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20 unless under the direct control and/or  
21 supervision of the certifying reporter.)

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